UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency **Office of Pesticide Programs**

Antimicrobials Division (AD)

November 3, 2011

DP BARCODE: 393847

MRID : 485764-01

SUBJECT: AW35-36
(Name of Product)

EPA File Symbol.: 1258-RGUE

DOCUMENT TYPE: Product Chemistry Review

Manufacturing-use [ ] OR End-use Product [x]

INGREDIENTS:

PC Code(s)	CAS Number	Active Ingredient(s):
081405	87-90-1	Tri-chloro-s-triazinetrione
024401	7758-99-8	Copper sulfate pentahydrate

TEST LAB: Arch Chemicals, Inc.

SUBMITTER: Arch Chemicals, Inc.

GUIDELINE: Product Chemistry Group A and B

ORGANIZATION: AD\PSB\CTT

REVIEWER: Earl Goad

APPROVED BY: Karen P. Hicks

APPROVED DATE: November 3, 2011

COMMENT:

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency **Office of Pesticide Programs**

Antimicrobials Division (AD)

November 3, 2011

MEMORANDUM

SUBJECT: Product Chemistry Review for EPA Reg. 1258-RGUE
Product Name:AW35-36
DP Barcode: 393847

CODE: (A531) New Product, Identical or Substantially Similar in Composition

DATE DUE: January 8, 2012

FROM: Earl Goad, Biologist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

THRU: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

TO: Monisha Harris PM#32/Wanda Henson
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: Arch Chemicals, Inc.

PRODUCT FORMULATION FROM LABEL:

PC Codes	Active Ingredient(s):	% by wt.
081405	Tri-chloro-s-triazinetrione	93.5
024401	Copper sulfate pentahydrate	1.5
	Other Ingredient(s):	5.0
	Total:	100.0

BACKGROUND:

Arch Chemicals, Inc. has submitted an application for registration of a new end-use product EPA File Symbol 1258-RGUE "AW35-36". This product is for use as a swimming pool water sanitizer and algaecide. The product is produced by a non-integrated system. The sources of the active ingredient(s) Tri-chloro-s-triazinetrione and copper sulfate pentahydrate are from EPA registered source products.

Most of the product chemistry data supporting the registration of this product is cited from previously reviewed studies performed on a similar product, EPA Registration # 1258-1244 "Enduraclean Tablets".

The data package included the following documents, all are dated August 17, 2011 except where noted otherwise.

1. A letter from the applicant to EPA.
2. EPA Form 8570-1 (Application for Pesticide).
3. Confidential Statement of Formula (CSF) for the basic formulation and alternate A formulations
4. EPA Form 8570-35 (Data Matrix).
5. EPA Form 8570-37 (Self-Certification Statement for the Physical/Chemical Properties (PR Notice 98-1)).
6. Draft label, dated 8/01/2011;
7. OPPTS 830 Series Product Chemistry Study Documents
    a. Product Chemistry Group A document (MRID 485764-01) entitled "Formulation Process for Arch Enduraclean Tablets", dated August 25, 2010
    b. Product Chemistry Group A document (MRID 485764-02) entitled "Formulation Process for Arch Enduraclean Tablets Addendum 1", dated August 1, 2011., 2010

FINDINGS:

The subject product is substantially similar to EPA Reg# 1258-1244 with minor differences in some inert ingredients.

1. Confidential Statement of Formulation. The basic and alternative A CSFs dated August 17, 2011 appear to be complete and accurate. These CSFs are acceptable.

2. Product Label. The following revisions to the product label are recommended.

    a. Add the following sub-statements to the ingredient statement. The statements can be indexed to the specific active ingredient to which they apply. "Available Chlorine 84%" and "Metalic copper equivalent 0.38%"

    b. Under the "Storage & Disposal" section of the product label, provide instructions for disposing of unused product.

    c. Place the "Storage & Disposal" and "Emergency Handling" sections in a text box/boxes for prominence.

d. Add subheadings within the "Storage & Disposal" section, such as "Pesticide Storage" and "Pesticide Disposal and Container Handling."

e. Under the "Storage & Disposal" section of the product label, add instructions that specify what to do if the product leaks or spills from the product container.

3. Product Chemistry
   a. Product Chemistry Group A: - Product Identity and Composition.
      i.

      ii. The OPPTS 830.1800 (Enforcement Analytical Method) was cited from a study assigned MRID 455767-01. That cited document did not contain a complete method description for analysis of this product for the active ingredient. A complete stand alone validated method is a guideline requirement. A more complete procedure was provided by citation of MRID#: 482996-01. A revised Data Matrix dated November 3, 2011 was received incorporating this change. The cited enforcement method is found to be acceptable.

   b. Product Chemistry Group B: - Physical and Chemical Properties

      i. Because the active ingredients in the product are obtained from EPA Registered products, according to PR Notice 98-1, it is acceptable for the registrant to self certify the Group B requirements. The results provided on the Form 8570-36 dated August 17, 2011 are found to be acceptable.

      ii. The two exceptions listed on the self certification data form were guidelines OPPTS 830.6317 (Storage Stability) and OPPTS 830.6320 (Corrosion Characteristics) requirements. The results of a minimum of 1 year from a GLP-compliant storage stability and corrosion characteristics study must be provided. The form reports that these studies are underway and will be submitted for review upon completion.

CONCLUSION:

The basic and alternate A CSFs dated August 17, 2011 are found to be acceptable. Several changes are recommended for the product label. Recommended label changes are subject to the discretion of the regulatory reviewer in their negotiations with the registrant. The product chemistry group A and B data requirements have been satisfied with the exception of the one year storage stability and corrosion characteristics studies which are to be submitted upon completion..

PRODUCT CHEMISTRY REVIEW

I. CONFIDENTIAL STATEMENT OF FORMULA

a. Type of formulation and source registration:

- Non-integrated formulation system — Yes [X] No [ ]
- Are all TGAIs used registered? — Yes [X] No [ ]
- Integrated formulation system — Yes [ ] No [X]
- If "ME-TOO," specify EPA Reg. No. of existing product: 1258-1244

b. Clearance of inerts for non-food or food use:
The product is not cleared for food use under 40 CFR §§180.940.. This product is not intended for food use.

Note: All formulation components are listed on the EPA document "Inert Ingredients Permitted for Use in Nonfood Use Pesticide Products," last updated on March 28, 2010 and available at http://www.epa.gov/opprd001/inerts/inert_nonfooduse.pdf.

c. Physical state of product: *Solid*

d. The chemical IDs and analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in 830 Series, Group B. Yes [X] No [ ]

e. The NCs and CLs are acceptable. Yes [X] No [ ]

f. Active ingredient(s)	NC (%)	LCL (%)	UCL (%)
Trichloro-s-triazinetrione	93.5	90.7	96.3
Copper sulfate pentahydrate	1.50	1.43	1.58

g. For products produced by an integrated formulation system:

- Do all impurities of toxicological significance have a UCL?
  Yes [ ] No [ ] Not applicable [X]
- Have all impurities of ≥ 0.1% in the product been identified?
  Yes [ ] No [ ] Not applicable [X]

II PRODUCT LABEL

a. The active ingredient(s) statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA. Yes [X]No [ ]

b. The formula contains one of the following:

- 10% or more of a petroleum distillate: Yes [ ] No [X]
- 1.0% or more of methyl alcohol: Yes [ ] No [X]
- sodium nitrite at any level: Yes [ ] No [X]
- a toxic List 1 inert at any level: Yes [ ] No [X]
- arsenic in any form: Yes [ ] No [X]

c. If "yes" to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes [ ] No [ ] Not applicable [X]

d. Appropriate warning statement(s) regarding flammability or explosive characteristics of the product are listed on the label.
Yes [X] No [ ]

e. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.
Yes [X] No [x]

Note: Disposal options for unused pesticide and for the container must be identified. See the Findings Product label

f. The product requires an expiration date at which time the NC falls below the LCL (based on the 1-year storage stability data or other information).
Yes [X] No [ ]

Note: Results for a minimum of 1 year from a GLP-compliant storage stability study must be provided.

Table A:
Product Chemistry (Series 830, Group A)

Data Requirements	Acceptance of Information	MRID No.
830.1550 Product Identity[1]	A	485764-01 485764-02 and CSF
830.1600 Description of Materials	A	485764-01 485764-02 and CSF
830.1620 Production Process[2]	NA	
830.1650 Formulation Process[3]	A –	485764-01
830.1670 Formation of Impurities[4]	A –	485764-01
830.1700 Preliminary Analysis[5]	*[Not required for products produced by a non-integrated system.]*	
830.1750 Certified Limits[6]	A – Standard certified limits (or limits within the standard certified limit range) were proposed. A – A signed certification statement was provided, as requested under OPPTS 830.1750(g). as a note at the bottom of the CSFs	CSF
830.1800 Enforcement Analytical Method[7]	A –.	Data Matrix cites 482996-01
830.1900 Submittal of Samples	*[Samples are to be provided on a case-by-case basis for end-use products.]*	

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

[1]See Confidential Appendix A for additional information.
[2]For MP/EP products produced by an integrated formulation system.
[3]For products from a TGAI or MP.
[4]May be waived unless actual/possible impurities are of toxicological concern.
[5]Five batch analysis required for products produced by an integrated formulation system.
[6]If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.
[7]Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

Table B:
Physical and Chemical Characteristics (Series 830, Group B)

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.6302 Color	NA	*[Not required for end-use products.]*	
830.6303 Physical State	A	The product is a solid.	EPA Form 8570-36
830.6304 Odor	NA	*[Not required for end-use products.]*	
830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	NA	*[Not required for end-use products.]*	
830.6314 Oxidation/ Reduction; Chemical Incompatibility	A	The product shows no reactivity with water, potassium permanganate, zinc powder, or ammonium phosphate. Note: The product label states that the product is a strong oxidizing agent. The product label states that the water should not be added to the product, rather the product should be added to water.	EPA Form 8570-36
830.6315 Flammability/ Flame Extension	NA	The product is a solid.	
830.6316 Explodability	A	Note: The product label states that the product can react with other materials to cause fire, explosion, and the release of toxic gases; and that exposure to heat can cause the product to rapidly decompose, leading to fire, explosion, and the release of toxic gases.	Label
830.6317 Storage Stability	G	Storage stability information will be reported later.	EPA Form 8570-36
830.6319 Miscibility[1]	NA	The product is a solid.	
830.6320 Corrosion Characteristics	G	Corrosion characteristics information will be reported later.	EPA Form 8570-36
830.6321 Dielectric	A	The product is not intended	EPA

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
Breakdown Voltage		for use in the vicinity of electrical equipment or conduits.	Form 8570-36
830.7000 pH[2]	A	The pH of the product was reported to be 2.12 (1% in water).	EPA Form 8570-36
830.7050 UV/Visible Absorption	NA	*[Not required for end-use products.]*	
830.7100 Viscosity	NA	The product is a solid.	
830.7200 Melting Point/Melting Range	NA	*[Not required for end-use products.]*	
830.7220 Boiling Point/Boiling Range	NA	*[Not required for end-use products.]*	
830.7300 Density/Relative Density/Bulk Density	A	The density of the product was reported to be 1.62 g/cm^3.	EPA Form 8570-36
830.7370 Dissociation Constants in Water	NA	*[Not required for end-use products.]*	
830.7550/830.7560/830.7570 Partition Coefficient	NA	*[Not required for end-use products.]*	
830.7840/830.7860 Water Solubility	NA	*[Not required for end-use products.]*	
830.7950 Vapor Pressure	NA	*[Not required for end-use products.]*	

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

---

* Provide brief description, e.g., color – yellow or property value, e.g., density 1.25 g/cc. Unless otherwise indicated, the property should be at 25°C.

[1]If product is an emulsifiable liquid
[2]If product is dispersible with water